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Docket No. G-092US02CIP

Serial No. 10/071,645

Remarks

Claims 14-23, 29, 32-34, and 46 are pending in the subject application. By this Amendment, Applicants have canceled claim 46, amended claims 14, 18, 21, 22, and 29 and added new claims 47-52. Support for the amendments and new claims can be found throughout the subject specification and in the claims as originally filed. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 14-23, 29, 32-34, and 47-52 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

As an initial matter, Applicants gratefully acknowledge the Examiner's indication that claims 21, 23, 32, and 33 are objected to but would be allowable if rewritten into independent form to include the limitations of any base and intervening claims. Applicants gratefully acknowledge the Examiner's withdrawal of the rejections under 35 U.S.C. § 112, second paragraph, and certain of the rejections under 35 U.S.C. § 112, first paragraph.

Claims 14-20, 22, 29, 34, and 46 remain rejected under 35 U.S.C. § 112, first paragraph, as non-enabled. Claim 18 has been rejected as reading on transgenic animals. Applicants respectfully submit that this issue is now moot as the claim has been amended in accordance with the Examiner's suggestion and no longer reads on a transgenic animal. Applicants respectfully assert that claims 14-20, 22, 29, and 34 are enabled by the subject specification and traverse the other aspects of this rejection on the following grounds.

Claims 14-20, 22, 29, 34 and 46 were rejected under 35 U.S.C. § 112, first paragraph on the basis that the claims are not enabled by the subject application. The Office Action argues that the pending claims "are not limited to polynucleotide sequences that encode polypeptides that share at least 95% sequence identity to SEQ ID NO: 2, nor are the claims limited to polynucleotides that share at least 95% identity to the coding region of the polynucleotide the encodes the polypeptide of SEQ ID NO: 2 or that they retain a particular activity". Applicants respectfully submit that the claims are now directed to polynucleotides that encode polypeptides that bind to g34872 or CaM-KII and which have at least 95% identity to the polynucleotides of SEQ ID NO: 2. Applicants further submit that such claims are enabled by the subject application.

As discussed by the Patent and Trademark Office Board of Patent Appeals and Interferences: "The test [for enablement] is not merely quantitative, since a considerable amount of

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experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed". See *Ex parte* Jackson, 217 U.S.P.Q. 804, 807 (B.P.A.I. 1982) ("[t]he test [of enablement] is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine.") and *Ex parte* Erlich 3 U.S.P.Q.2d 1011 (B.P.A.I. 1982) (observing that although a method might be "tedious and laborious," such experimentation is nevertheless "routine" defining "routine" experiments as those which use known methods in combination with the variables taught in the patent to achieve the expected, specific, patented result). In this case, the claims recite polynucleotides that have at least 95% identity to the polynucleotides of SEQ ID NOs: 1 or 3 and which encode a polypeptide that binds to CaM-KII or g34782. Thus, the claims are directed to polynucleotides that have a particular structure (namely a polynucleotide sequence that is at least 95% identical to the specified SEQ ID NO: and which encode a polypeptide that has a specified biological activity (the ability to bind to CaM-KII or g34782). Applicants respectfully submit that the specification provides adequate guidance with respect to the direction in which experimentation should proceed to practice those embodiments directed to polynucleotides having at least 95% identity to SEQ ID NOs: 1 and 3 which encode polypeptides that bind to g34782 or CaM-KII. For example, the specification teaches various assays for measuring the ability of a PAPAP polypeptide's interaction with CaM-KII or with g34782 (see specification at paragraphs 295-296). While it may be necessary to generate a large number of variant polynucleotides, methods for making the same, transfecting cells, and determining the interaction of PAPAP derived polypeptides with g34782 or CaM-KII are taught in the specification and/or known to those skilled in the relevant art. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested as it is respectfully submitted that the as-filed specification teaches the requisite variables in combination with the necessary methods for identifying and making polynucleotides as specified in the claims to achieve the recited expected and specific result.

Claims 14-20, 22, 29, 34, and 46 remain rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had

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possession of the claimed invention. Applicants respectfully assert that there is adequate written description in the subject specification to convey to the ordinarily skilled artisan that they had possession of the claimed invention. The Office Action argues that "[T]hat the factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, and any combination thereof".

Applicants respectfully submit that an analysis of the as-filed specification with respect to these factors would indicate that the claimed invention meets the written description requirement. For example, the complete sequences of SEQ ID NOs: 1 and 3 are set forth in the as-filed specification and the claims recite polynucleotides that have at least 95% identity to these polynucleotides (see Sequence Listing). Methods of making the claimed polynucleotides and the polypeptides encoded thereby are also taught in the as-filed specification (see pages 20-22 and 37-42). Additionally, the specification clearly indicates that polynucleotides within the scope of such claims include those that are "silent" or do not change the coding sequence of the polypeptide (see paragraph 62). It is also submitted that one skilled in the art would have recognized those sections of SEQ ID NO: 2 that could be modified via substitution of up to four amino acids without affecting the ability of the polypeptide to inhibit CaM-KII as discussed in a previous response (relating to the factors identified as physical and/or chemical properties, functional characteristics, and structure/function correlation) and that this knowledge would have allowed one skilled in the art to avoid deleteriously changing those nucleotides of SEQ ID NO: 1 or 3 that encode this section of the polypeptide. Thus, it is respectfully submitted that the claims and this application satisfy the requirements of 35 U.S.C. § 112, first paragraph, and that this rejection should be reconsidered and withdrawn.

Claims 14-20 are rejected under 35 U.S.C. § 102(e) as anticipated by Kaser *et al.* (U.S. Patent No. 6,222,027). The Office Action indicates that Kaser *et al.* teach a nucleic acid that comprises nucleotides 2158-2218 of SEQ ID NO: 3 as claimed herein. Applicants respectfully assert that the patent does not anticipate the claimed invention as that portion of claim 14 rejected under this section has been amended. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(e) is respectfully requested.

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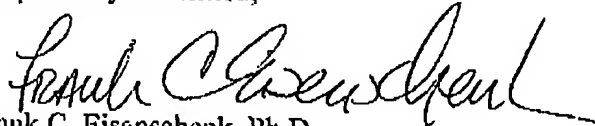
It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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